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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/549,848	04/14/2000	Michael Lassner	17133/02/US	9155

7590 01/03/2002

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	PAPER NUMBER
1638	19

DATE MAILED: 01/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/549,848	LASSNER ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 11-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 11-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of SEQ ID NO:1 in Paper No. 18 is acknowledged. The traversal is on the ground(s) that the Patent Office has not proven that an undue burden would be imposed by the search and examination of more than one sequence. This is not found persuasive because databases and resource allocations at the PTO have changed such that the examination of more than one sequence on the merits in the instant application would present a burden on PTO resources.

2. The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 10, is attached to the instant Office action.

Specification

4. The disclosure is objected to because of the following informalities: the text on page 42 refers to the expression of "ATAT2". "ATAT2" is not disclosed elsewhere in the specification, and it is apparent from the specification that the text was meant to refer to "ATPT2".

5. Appropriate correction is required.

Claim Objections

6. Claims 35, 38, 40 and 41 are objected to because of the following informalities: the claims recite the SEQ ID NOS of nonelected inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-4, 11-12, 13-18, 34, 36 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. The claims are drawn to isolated nucleic acids and nucleic acid constructs encoding prenyltransferases. The claims are also drawn to plant cells comprising said constructs.

10. However, the specification does not set forth what specific structural or physical features define the claimed isolated nucleic acids. The specification only discloses the structure of the *Arabidopsis* aromatic prenyltransferase nucleic acid sequence of the elected invention, SEQ ID NO:1, and that this nucleic acid encodes a functional protein as evidenced by its ability to complement a *Synechocystis* knockout mutant (pages 40-41). The identities of the claimed isolated nucleic acids are uncertain. One skilled in the art could not predict the specific structural features of the claimed isolated nucleic acids encoding prenyltransferases. The specific physical features of the claimed isolated nucleic acids cannot be ascertained in the absence of information about the functional activities of the nucleotide sequences they comprise.

11. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states:

> "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA ... Accordingly, the specification does not provide a written description of the invention ..."

12. Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed isolated nucleic acids, one skilled in the art would not have been in possession of the claimed plant cells at the time this application was filed.

13. Claims 1-4 and 11-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing alpha, gamma, delta, and total tocopherol content in *Arabidopsis* seeds by transforming *Arabidopsis* with SEQ ID NO:1, and while being enabling for a method of increasing the level of alpha tocopherol content in the *Synechocystis* knockout mutant slr1736 by transforming slr1736 with SEQ ID NO:1, does not reasonably provide enablement for other methods using other isolated nucleic acids encoding other prenyltransferases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

14. The claims are drawn to isolated nucleic acids and nucleic acid constructs encoding prenyltransferases. The claims are also drawn to plant cells comprising said constructs. Additionally, the claims are drawn to methods of altering tocopherol content in a cell, producing a tocopherol compound of interest in a cell, and increasing biosynthetic flux in a cell toward tocopherol production, by transforming cells with said constructs.

15. The specification only discloses a method of increasing alpha, gamma, delta, and total tocopherol content in *Arabidopsis* seeds by transforming *Arabidopsis* with SEQ ID NO:1 (pages 41-42 *Example 5* and *Figure 24*). The specification also discloses a method of increasing the level of alpha tocopherol content in the *Synechocystis* knockout mutant slr1736 by transforming

slr1736 with SEQ ID NO:1 (pages 40-41 *Example 4D*). The specification does not disclose other methods of affecting tocopherol by using other isolated nucleic acids encoding other prenyltransferases.

16. Guidance for making and using the claimed invention is necessary for enablement because the ability of a nucleic acid encoding a particular enzymatic activity from one source to functionally substitute for another nucleic acid encoding the same enzymatic activity from another source is highly unpredictable.

17. Shewmaker et al. teach that overexpression of bacterial phytoene synthase in canola increases β-carotene content (The Plant Journal, 1999, Vol. 20, No. 4, pages 401-412, see page 405 *Table 1*). Burkhardt et al. teach that overexpression of daffodil phytoene synthase in rice increases phytoene content but not β-carotene content (The Plant Journal, 1997, Vol. 11, No. 5, pages 1071-1078, see page 1075 column 2 first full paragraph).

18. Given the unpredictability of any isolated nucleic acid encoding a prenyltransferase to functionally substitute for SEQ ID NO:1, the absence of guidance in the specification for making and using other isolated nucleic acid encoding functional prenyltransferases, the lack of working examples, and given the breadth of the claims which encompass any nucleic acid encoding any prenyltransferase as well as methods involving said nucleic acid sequences, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

19. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20. Claims 19, 24 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

21. Regarding claim 19, the term "alteration" renders the claim indefinite because it is unclear in what way the tocopherol content of the host cell is altered.

22. Regarding claim 24, the phrase "a tocopherol of interest" renders the claim indefinite because it is unclear which tocopherols are encompassed by the claim.

23. Regarding claim 29, the phrase "increasing the biosynthetic flux in a host cell toward tocopherol" renders the claim indefinite because it is unclear what constitutes increasing the biosynthetic flux in a host cell toward tocopherol.

Claim Rejections - 35 USC § 102

24. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

25. Claims 1-4 and 13-15 and 19-20, are rejected under 35 U.S.C. 102(b) as being anticipated by Kuntz et al. (1992, The Plant Journal, Vol. 2, No. 1, pages 25-34, Applicant's IDS).

26. The claims are drawn to isolated nucleic acids and nucleic acid constructs encoding eukaryotic plant prenyltransferases, and to a method comprising transforming a prokaryotic host cell with a construct comprising a nucleic acid encoding a prenyltransferase.

27. Kuntz et al. teach isolated nucleic acids and nucleic acid constructs encoding a *Capsicum annuum* prenyltransferase, and a method comprising transforming a prokaryotic host cell with a construct comprising a nucleic acid encoding a prenyltransferase.

28. Accordingly, claims 1-4 and 13-15 and 19-20 are anticipated by Kuntz et al.

29. Claims 1-4, 13-16, 19-20 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhu et al. (1997, Plant Molecular Biology, Vol. 35, No. 3, pages 331-341, Applicant's IDS).

30. The claims are drawn to isolated nucleic acids and nucleic acid constructs encoding eukaryotic plant prenyltransferases from *Arabidopsis*, and to a method comprising transforming a prokaryotic host cell with a construct comprising a nucleic acid encoding a prenyltransferase.

31. Zhu et al teach isolated nucleic acids and nucleic acid constructs encoding a prenyltransferase from *Arabidopsis*, and a method comprising transforming a prokaryotic host cell with a construct comprising a nucleic acid encoding a prenyltransferase.

32. Accordingly, claims 1-4, 13-16, 19-20 and 34 are anticipated by Zhu et al.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
December 19, 2001

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800